BIOMECHANICAL COMPARISON OF SIX INTERNAL STABILIZATION CONSTRUCTS FOR FIXATING HIGHLY COMMINUTED CANINE DIAPHYSEAL FEMORAL FRACTURES.

By

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LIST OF ABBREVIATIONS / NOMENCLATURE

AC	Axial Compression
AO	Arbeitsgemeinschaft fur Osteosynthesefragen (a.k.a. ASIF)
ASIF	Association for the Study of Internal Fixation
CCB	Caudal-Cranial Bending
DCP	Dynamic Compression Plate
EC	Eccentric Compression
FEM	Femur; intact cadaveric femur
IFM	Interfragmentary motion
IN	Interlocking Nail
IM	Intramedullary
LC	Limited Contact - Dynamic Compression Plate (LC-DCP)
LCR	LC-DCP-rod Construct
LP	Lengthening Plate
MLB	Medial-Lateral Bending
PR	Plate-rod Construct (a.k.a. in literature: Pin/Plate, Plate/Pin, Rod/Plate)
TL	Torsional Loading; Rotational Force
Type 32-C3	Unger type 32-C3 fracture; Highly comminuted, non-reconstructable, femoral diaphyseal fracture
USA	United States of America

LIST OF ABBREVIATIONS / NOMENCLATURE

Units of measurement

deg	Degree (0.0175 radians)
Kg	Kilogram
Mm	Millimeter
N	Newton (0.0102 Kg, 0.225 pound)
Nm	Newton-meter (measurement of bending moment)
N/mm	Newton per millimeter (measurement of compressive stiffness)
Nm/deg	Newton-meter per degree (measurement of bending or torsional stiffness)

CHAPTER 1

INTRODUCTION

Femoral fractures are common in dogs and cats, accounting for one-quarter to one-third of veterinary fracture repairs.[6,10,60,84] Femoral fractures can result from high-energy trauma (e.g. motor vehicle accident or gunshot wound) with complex loading patterns of excessive caudal-cranial and medio-lateral bending (CCB, MLB), torsion (TL), and axially compressive (AC) forces. Highly comminuted fractures are complicated by extensive soft tissue injury and resulting reduction of blood flow to bone fragments. Highly comminuted mid-diaphyseal femoral fractures are often difficult to reconstruct and present increased technical challenge for the surgeon. High fracture repair complication rates in humans and animals are attributed to the use of traditional methods of open reduction, bone reconstruction, and internal stabilization with dynamic compression plates (DCP).[7] Complications include implant loosening, sequestrum formation, osteomyelitis, delayed union or malunion, poor limb function, and fracture disease.[47,60,72,84] In light of these problems, new osteosynthesis concepts and methods of comminuted fracture repair have developed.

The concept of biologic osteosynthesis has received increasing popularity, investigation, and application over the past decade.[5,23,48,68,69] The goal of fracture treatment is to achieve fracture healing, functional bone alignment, and return to function of the effected leg.[1a] A fractured bone does not have to be anatomically reconstructed to achieve these goals. Biologic osteosynthesis advocates functional alignment as opposed to anatomic reconstruction, closed or minimal approach reduction, preservation of fragment vascularity and soft tissue coverage, and rigid stabilization.[5,68] The application of such principles has proven beneficial in terms of higher fracture repair success rates, lower complication rates, and more rapid return to functional limb use.[23,48]

The problem incurred using biologic osteosynthesis principles is that fixation devices span the fracture gap and are subjected to the entire load of the limb (buttress effect). Such buttress repair constructs must be the strongest of all fracture repairs because no distribution of forces acting on the bone occurs between the bone and the implant (load sharing). . The traditional use of bridging DCP plates continues; however, the application of these plates in buttress predisposes them to failure in unfilled screw holes within the fracture gap.[6,48] To improve repair stability, new stabilization constructs have been recommended to include the addition of an intramedullary pin to standard buttress DCP plating (plate-rod construct)(PR), the use of limited contact - dynamic compression plates

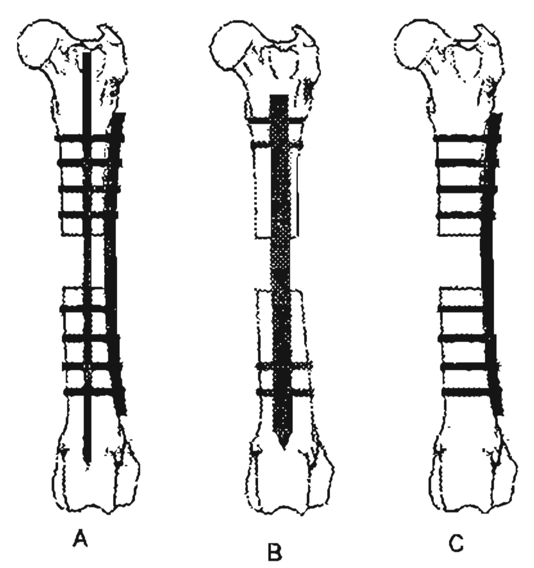

Figure 1. Fixation Constructs. Cranial view of three mid-diaphyseal femoral ostectomy-fixation constructs. A. Plate-rod (LCR, PR). B. Interlocking Nail (IN). C. Plate (DCP, LC, LP).

(LC-DCP)(LC), the use of bone lengthening plates (LP), and the use of interlocking nails (IN).[8,26,27,29,34,40,41,48,59,64 69] (Fig.1)

Improved bone stabilization appliances and techniques allow the biologic osteosynthesis of non-reconstructable diaphyseal fractures in buttress by producing more stable constructs. Plate-rod constructs have demonstrated doubled bending resistance by the application of an IM pin of 30-50% isthmus diameter in addition to standard DCP repair.[40,41] Limited contact – dynamic compression plates were designed by the AO Research Foundation as a new plating alternative for biologic osteosynthesis.[60] These plates have a complex contouring design, which creates consistent cross-sectional area across the entire length of the plate, including screw-hole sections. They also offer more uniform bending characteristics and do not concentrate forces at screw holes, where DCP plates usually break. Lengthening plates, lacking screw holes at mid-plate, have been recommended because they allow gap bridging without force concentration in fracture gap screw holes.[34,59,64] Interlocking nail systems are IM pins with proximal and distal screw holes for securing the nail in the medullary canal. Interlocking nails, being fixed in the medullary cavity along the bone's longitudinal-neutral axis, have the mechanical advantage of having zero moment arm to force opposition.[76] The advantages and use of LC-DCP and LP for use in comminuted mid-diaphyseal femur fracture stabilization have been discussed, but not investigated.[40] The use of LC-DCP-rod constructs (LCR) has neither been described, nor investigated. The use of IN stabilization of femoral fractures has been discussed and investigated;[8,9] however, not all fracture forces were studied, and the Numedic IN system (Numedic SA Ltd., Collet, France) studied is not available in the USA.

The objective of this study was to biomechanically compare the relative strengths of intact cadaveric canine femurs (FEM) and six internal stabilization constructs (IN, LP, DCP, LC, PR, and LCR) that might be used to fixate highly comminuted diaphyseal femoral fractures using biologic osteosynthesis principles. Intact FEM and stabilized gap-ostectomized femurs were subjected to nondestructive physiologic loading conditions with four isolated forces (EC, AC, CCB, MLB) to determine construct stiffness and fracture gap interfragmentary motion (IFM). No study to date has endeavored to simultaneously compare multiple femoral buttress fixation constructs (DCP, PR, LC, LCR, LP, IN) using all four fracture distraction forces (EC, AC, CCB, MLB). We hypothesized that FEM would outperform all appliances and that the stabilized gap-ostectomized femur constructs would perform predictably such that buttress plates were relatively weaker, plate-rod combinations were stronger, and IN and LP strongest.[21,63,70,73,76]

CHAPTER 2

LITERATURE REVIEW

Introduction

A literature search was conducted using MEDLINE and the Veterinary Information Network's journals index. Key topical descriptors included femoral fractures, biological osteosynthesis, bridging technique, in vitro biomechanical testing, bone storage, plate-rod constructs, interlocking nails, limited contact - dynamic compression plates, and lengthening plates. Dynamic compression plating was not reviewed as a critical subject, due to its acceptance in veterinary orthopedics, unless DCP plating was used in biomechanical comparison to other evaluated constructs. Veterinary studies received greater attention; however, human literature was reviewed for biomechanical testing guidelines and results. Definitive veterinary surgical texts were also consulted. A bibliographic scrub of full text journal articles and orthopedic texts uncovered additional important citations. Commercial manufacturers were consulted for proprietary biomechanical data. Commercial manufacturer sites are accessible via Internet. In total, the search identified approximately 150 manuscripts for evaluation; 87 are included in the reference list.

Femur fractures

Femoral fractures are common fractures in dogs and cats, accounting for one-quarter to one-third of veterinary fracture repairs.[6,10,60,84] Femoral fractures are usually the result of high-energy trauma (motor vehicle accident, gunshot wound) with complex loading patterns of excessive caudal-cranial and medio-lateral bending (CCB, MLB), torsional loading (TL), and compressive (AC, EC) forces.[21,70,73,84] Veterinary orthopedists are presented with complex, highly comminuted fracture patterns, which are complicated by extensive soft tissue injury and reduction of blood flow to bone fragments. Highly comminuted mid-diaphyseal femoral fractures (Unger Type 32-C3)[80] are often difficult to reconstruct and present increased technical challenge for the surgeon. Femoral fractures are the a severe test on internal fixation in veterinary patients.[47,60,72,84] A decade ago many such fractures would be repaired with anatomic reconstruction of the fragments, limb shortening with standard fixation, or segmental allograft replacement and internal fixation splinting.[64] Reduction of such fractures requires significant soft tissue disruption.[69] High veterinary fracture repair complication rates are attributed to the use of traditional methods of open reduction, bone reconstruction, and internal stabilization with dynamic compression plates (DCP).[12,35] In the human literature, while the overall incidence of acute and fatigue plate failure during extremity fracture stabilization is quite low (2.4%),[12] the failure rates for femoral shaft plating as high as 21% have been reported.[35] The femur also has the highest rates of nonunion and osteomyelitis of all fractures in veterinary patients.[60,72] Other complications, which may be attributed to inadequate stabilization, extensive soft tissue damage, and loss of periosteal and intramedullary blood supply include implant loosening, sequestrum formation, delayed union, poor limb function, and fracture disease.[46,47,60,72,84] In light of these problems, new osteosynthesis concepts and methods of comminuted fracture repair have developed.

Biological osteosynthesis

The concept of biologic osteosynthesis has received increasing popularity, investigation, and application over the past decade.[5,23,48,68,69] The goal of fracture treatment is to achieve fracture healing, functional bone alignment, and return to function of the effected leg.[6] A fractured bone does not have to be anatomically reconstructed to achieve these goals. Traditional methods of mechanical fracture treatment (the Carpenter's approach)[68] are being replaced with biological fracture treatment methods (the Gardener's approach)[68] when anatomic reduction and appliance-bone load-sharing cannot be achieved without substantial disruption of the bone's soft tissue supporting structures. Biologic osteosynthesis advocates functional alignment as opposed to anatomic reconstruction, closed or minimal open approach ("open but do not touch")[68] reduction, preservation of fragment vascularity and soft tissue coverage, less traumatic construct application, rigid stabilization, and progressive destabilization, when applicable. The application of such principles has proven beneficial in terms of higher fracture repair success rates, lower complication rates, and more rapid return to functional limb use. In a comparison of fragment reconstruction and DCP fixation with bridging plate fixation using biologic fracture treatment principles in 35 dogs,[48] dogs treated with bridging plate techniques had shorter operative periods and demonstrated faster clinical healing. Fragment reconstruction techniques showed radiographic evidence of healing at 15.1 weeks, while bridging techniques showed radiographic evidence of healing at 10.5 weeks. In a similar study, comparing 47 dogs with tibial fractures. treated with open reduction - plate stabilization or closed reduction - external skeletal fixation (ESF), closed reduction resulted in shorter operative periods and fewer complications.[23] No differences in healing times were noted, possibly due to proportionately less rigid ESF stabilization.[23]

The problem incurred using biologic osteosynthesis principles is that fixation devices span the fracture gap (bridging) and are subjected to the entire load of the limb (buttress effect). Such buttress repair constructs must be the strongest of all fracture repairs. The traditional use of bridging DCP plates continues; however, the application of these plates in buttress predisposes them to failure in unfilled screw holes within the fracture gap.[59,76] To improve repair stability, new stabilization constructs have been recommended to include the addition of an IM pin to standard buttress DCP plating (PR), the use of limited contact - dynamic compression plates (LC-DCP), the use of lengthening plates (LP), and the use of interlocking nails (IN).[8,26,27,29,34,40,41,48,59,64,69]

Fixation constructs

Buttress-plate and Plate-rod constructs

Modern bone plating began in the early 1960s and has continued to grow in implementation and investigation through the efforts of the Swiss Arbeitsgemeinschaft fur Osteosynthesefragen (AO) and the Association for the Study of Internal Fixation (ASIF) (USA counterpart). This group has developed plate designs, instrumentation, and standardized techniques has made internal fixation with bone plates a versatile, popular, and successful alternative for internal fixation of most long bone fractures in human and veterinary patients.[53,72] The properly applied plate effectively resists all disruptive fracture forces: axial compression, bending, shear, tension, and torsional forces.[73] Bone plating allows early return to function via rigid stabilization of reconstructed fractured bone.[72] Bone plating, due to lack of alternatives, has traditionally been the fixation method of choice for femoral fractures in dogs.[6,72]

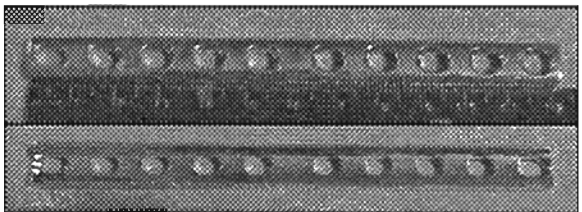

Figure 2. Dynamic Compression Plate. 3.5 mm, 10 hole, DCP.

The dynamic compression plate (DCP) (Fig. 2) was introduced in 1969,[4] and has been the standard internal fixation plate for the past three decades. The main problem with the use of a DCP in buttress to span an open fracture gap is that plate stress concentrates in unfilled screw holes, and the plate preferentially bends at a fracture gap hole.[6,40,46,59,71,73] Plates are also more effected by repeated bending stress (fatigue failure), than IM devices, due to their eccentric placement off the neutral axis of the bone (moment arm).[70,73] Other, reported features of current biologic plating theory include: induction of osteoporosis through interference with cortical perfusion, weak bone lamellae about the bone plate interface, and lack of screw placement flexibility due the DCP's extended middle section (without holes) and one-way compression holes.[69,71] For these reasons. the DCP has not been totally successful in the repair of highly comminuted femoral fractures[35] and is being phased out of use in lieu of the LC-DCP.[69,71]

Since buttress plating of non-reducible fracture gaps with uncontrolled compression of the contralateral side of the fracture can lead to early plate fatigue failure, the plate-rod construct has been recommended.[40,73] The addition of an IM pin, occupying 50% of the marrow cavity, to a buttress plate construct reduces plate strain by a factor of two and increases fatigue life of the plate by 10-fold.[40] Further study demonstrated that optimal pin size to encourage healing, allow screw placement, and minimize stress protection is between 35% and 40% of IM diameter.[41] A plate-rod construct is recommended whenever a plate is to be used, and anatomic fracture reduction Is not possible.[40,73] An additional advantage of the PR is that it can be destabilized at 6-8 weeks by removing the IM pin to encourage fracture healing.[47]

Limited contact plates (Fig. 3)

Limited contact - dynamic compression plates are bone plates specifically designed by AO as a replacement for DCPs for use with biologic plating techniques.[48,55,69,71] They are designed to minimize plate to bone contact and to encourage blood flow beneath the plate, as compared to standard DCP plates. This is achieved by having an undercut surface with a more trapezoidal, than rectangular, cross-sectional area. In theory, in the long term, this reduces plate associated osteoporosis by increasing cortical perfusion around the plate and by minimizing stress protection by the plate. However, both of these claimed effects have been investigated and disputed.[44,45] Additionally, the LC-DCP's trapezoidal shape and cutout between screw holes allows for equivalent cross-sectional area across all sections of the plate, reducing stress concentration at screw holes and allowing for uniform bending stiffness. This is in contrast to DCPs which deform preferentially at open screw holes. The screw holes are designed for more flexible use by allowing dynamic compression in either direction; however, special guides are required to achieve this effect. Holes are also equally spaced to allow purchase of fracture gap fragments. Finally, the undercut shape allows for more screw angulation than DCP plates (up to 40°).

Biomechanical comparison of LC-DCPs and DCPs has been performed. In two

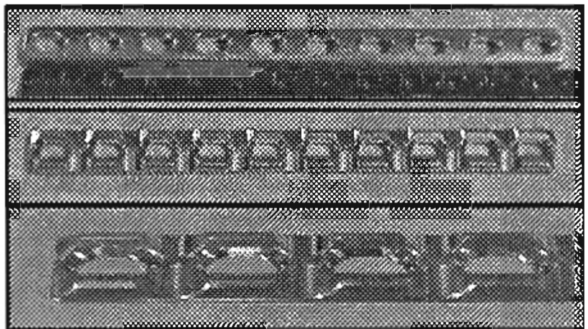

Figure 3. Limited Contact - Dynamic Compression Plate. 3.5 mm, 10 hole, LC-DCP.

studies, 4.5mm titanium LC-DCPs (tLC) and 4.5mm stainless steel DCPs (sDCP) had similar bending stiffness in a 1mm gap model,[1] and 4.5mm tLC and 4.5mm titanium DCPs (tDCP) had nearly identical bending stiffness in a closed gap model.[59] These studies lead to an expectation that DCPs should perform similarly to LC-DCPs. In a study of radial bone fracture fixation, Jain[43] determined that using a closed-gap osteotomy model, no differences in construct bending stiffness existed between 3.5mm sDCP, tDCP, steel LC-DCPs (sLC), or tLC. However, with a small open-gap model the stiffness and yield of sLC was better than tLC, and the stiffness and yield of sDCP was better than sLC. In another recent study, unmounted 3.5mm sLC were only 2/3 as stiff as unmounted 3.5mm sDCP in 4-point bending.[54] The expectation is that naked plate bending should be a more representative predictor of the plates' performances when placed in buttress across a large, open fracture gap.

Lengthening plates (Fig. 4)

Vacant screw holes in DCP plates result in weak points by concentrating stress, and they contribute to plate fatigue and failure. When a DCP is placed on a Type 32C3 fracture, bending causes a fulcrum effect, which concentrates excess force on the unfilled screw holes, resulting in acute or fatigue failure of the plate.[6] The probability of fatigue failure increases with gap size, because healing time and total cyclic loading is increased proportionately.[59] To avoid this weakness of DCPs, lengthening plates (LP), have been recommended to provide increased implant strength at the fracture gap for buttress plating applications.[8,34,40,59,60] Lengthening plates were designed for stabilization of human femoral and tibial corrective osteotomies.[59] Lengthening plates have a solid central portion and no screw holes over the fracture/osteotomy gap (Fig. 4). Because of this, they have a very high area moment of inertia at the fracture gap,[63,76] and do not concentrate force at a single point along the plate.

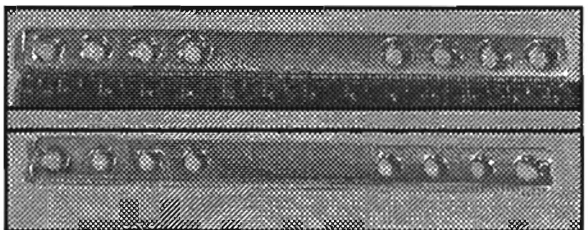

Figure 4. Bone Lengthening Plate. 4.5 mm, 8 hole, 30mm gap, LP.

Literature concerning lengthening plates is difficult to find. No published biomechanical studies are available. In one clinical case series,[54] LPs were used to repair eleven comminuted diaphyseal fractures including nine femora and two tibia. On average, patients were 75% weight bearing within 14 days and 100% weight bearing within 6 weeks. No implant failures occurred.

The time to radiographic union varied from 12 to 24 weeks, depending on fracture severity and reconstructability, and patient age. Only one complication (delayed union) occurred. In a similar report,[59] clinically excellent results were achieved in eight of ten dogs with highly comminuted femoral or tibial fractures. Three cases involved revision of failed DCP buttress plating. Only one complication (nonunion at one year) was noted.

Despite these advantages and successes, LPs have disadvantages, which limit their use.[34,59] Synthes-ASIF LPs are only offered in larger plate stock sizes (4.5mm narrow and broad),[*] so patient selection is limited to very large dogs. Their placement, even on larger dogs, usually requires substantial plate contouring and soft tissue reflection. Despite closer hole spacing, which allows more screws to be placed in the extant bone fragments, the LP's round screw holes do not allow the surgeon to angle screws except from the outer two holes. Additionally, they are somewhat more expensive than comparably sized DCPs.

Lengthening plates, using 4.5mm narrow plate stock, saw disuse following the introduction of the 3.5 mm broad DCP,[‡] because biomechanical studies questioned the relative biomechanical merits of 4.5 mm narrow versus 3.5mm broad plates.[49,77] These plates, along with 4.5 mm LPs use the same plate stock, but vary in screw size and placement. Johnston's comparison of 7-hole 3.5mm broad DCPs and 5-hole 4.5mm narrow DCPs demonstrated similar stiffness characteristics and cyclic fatigue failure, but improved catastrophic failure and screw pullout characteristics for the 3.5mm broad plate.[49]

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[*] Veterinary Orthopedics, Inc. offers LPs in smaller (3.5mm) sizes, which are not available through Synthes.

[‡] Personal communication, Sharon Kerwin, Texas A & M University, March 2000.

Interestingly, following the publication of this study, many surgeons adopted the broad plate over the narrow plate, and the use of lengthening plates reduced significantly. More recently, Silbernagel performed a similar study using a synthetic bone open-gap model and derived opposite conclusions, advocating the superiority of the 4.5mm narrow plate.[77] A LP with solid fracture gap coverage is intuitively stiffer than standard DCP or LC with screw holes in the gap.[64] Despite this fact, LPs have seen little use and no reported biomechanical investigation in veterinary medicine.

Interlocking nails (Fig. 5)

Interlocking nails are one of the most popular devices for fracture management in human orthopedics, and are gaining popularity among veterinary orthopedists.[46,57] Interlocking nails are IM pins with transverse screw holes proximally and distally for the insertion of interlocking screws. Veterinary INs ("Dueland" IN, Innovative Animal Products) are available for small animal use in 4.0 mm, 4.7 mm, 6.0 mm, and 8.0 mm sizes with one or two screw holes in each end (one or two distally and one or two proximally). The Model 11 8.0 mm nails use standard 3.5 mm cortical screws for locking bolts with a fragment interscrew distance of 11 mm (four screw nail). Placement of INs requires appropriately sized bone screws and screw placement equipment, as well as specialized IN equipment including

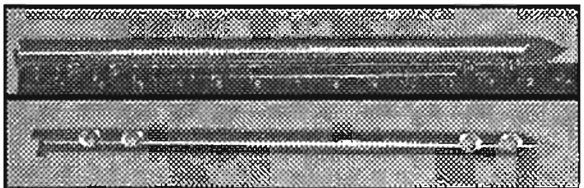

Figure 5. Interlocking Nail. 8mm x 140 mm, 11 series, IN.

reamers, jigs, drill and tap guides, guide trocar, insertion handle, and extension pieces.[46,57] Nail placement is technically demanding and is facilitated with intraoperative radiography (C-arm flouroscopy). The major limitation to IN use in veterinary patients has been nail size, which limited IN use to larger patients. Recently, smaller 4.0 mm and 4.7 mm INs have been manufactured to allow their use in smaller patients.[67] In small animal patients, IN fixation is indicated for mid-diaphyseal fractures of the humerus, femur, and tibia.[26,27,46,57,72,73]

A properly applied IN effectively resists all disruptive fracture forces: axial compression, bending, shear, tension, and torsional forces. The inherent structural strength of INs lies in their position along the bone's neutral axis and their cylindrical shape, which affords a large area moment of inertia (Appendix A). Mechanically, an IN is a hybrid between an IM pin and a bone plate, functioning as an "IM plate."[28] It has mechanical advantage over a bone plate because it is placed along the bone's neutral axis, as opposed to eccentric plate placement, which results in a force moment arm. Comparatively, INs have a greater area moment of inertia, and hence bending stiffness, than bone plates (Appendix X).[63,78] Theoretically, this combination results in proportionately better bending stiffness, resistance to torsional stress, and fatigue life. IM pins are equally resistant to bending loads applied from any direction because they are round.[46,57] Bending stress is more evenly distributed across the length of the IN, than a bone plate, which concentrates stress at screw holes.[7] INs resist torsional forces better than bone plates and IM pins.[25] Locking screws provide INs with resistance to axially compressive and torsional forces. However, screw holes are the weakest point on INs.[28] Screw holes of INs act as stress risers and are susceptible to bending, shear, and torsional forces. Unlike screws in bone plates, the screws placed through an IN do not interact rigidly with the nail; hence, locking screws do not reduce stresses at the screw hole.[76,87] Screws placed adjacent to fracture gaps (< 2 cm) produce stress risers, which predispose the nail to fatigue failure.[28] The use of a single screw at one end of the IN does not significantly alter construct stability and is preferred to placing a screw adjacent to the fracture site.[25,26,27,37] However, screw bending and nail breakout from cortical bone adjacent to screw holes has been reported.[79]

Clinical reports demonstrate successful IN use in veterinary patients. In one study of 134 fracture repair constructs using Dueland INs,[27] 75% healed uneventfully and 82% were judged to have excellent final outcomes. In a report of the use of a Huckstep type nail in 15 dogs, good limb function was obtained in less than three weeks, and fracture healing occurred in most dogs between 8 and 16 weeks post-operatively.[29] In another report of 13 comminuted fracture fixations in dogs and cats using a specially designed IN,[31] average time to weight-bearing limb use was three days, and no complications were encountered. One successful use of an IN for rigid stabilization following corrective opening-wedge osteotomy of an angular malunion,[38] with loss of cis- and trans-cortices, has been reported. Difficult contouring and placement of a DCP were avoided with IN use. One case of successful IN use as a revision following IM pin/cerclage femoral stabilization failure and osteomyelitis has been reported.[61] Using specialized devices, INs have also been successfully used in fracture fragment compression.[illegible]

One pair of similar studies has compared an 8 mm, 3 hole, the Numedic IN directly with the 3.5 mm broad, 10 hole DCP in eccentric compression and cantilever bending (CCB).[8,9] This study noted significantly greater stiffness and failure limits for IN over DCP in compression, despite little structural strength differences in bending. It also noted no differences in gap IFM with compression, but significantly more gap motion with DCPs in bending than IN. These studies were difficult to use comparatively because the investigators used non-standard bending methods, reported their results in incorrect units [compressive and bending stiffness both as Newtons (N) instead of Newton-meters (Nm) and Newton-meters per degree (Nm/deg), respectively], and failed to describe their methodology in sufficient detail to allow reader data transformation. This author holds these results in question because the investigators appeared more interested in validating their new optoelectric measuring device than reporting biomechanical data and some of their measurements appear out of acceptable ranges.

The biomechanical advantages of IN stabilization, usually concurrent with biologic osteosynthesis, have resulted in lower implant failure rates.[25,28,73] Clinically, nail breakage occurs rarely, at screw holes. Error in IN placement technique is the most common cause for IN failure. Fatigue failure at a screw hole has been reported following inadequately sized nail placement and screw placement adjacent to the fracture site.[26,27,46,57] The proximal screw hole in the distal fragment is the most common breakage site.[76,57] Screw failure also occurs.[46]

Conclusions

This literature search was performed to investigate the role of biological osteosynthesis and bridging technique in fracture management, and to gain biomechanical and clinical information relating to the use of plate-rod constructs, interlocking nails, limited contact - dynamic compression plates, and lengthening plates. Generally, descriptive and clinical data concerning each of the investigated appliances is available, but relevant biomechanical data is rare. The advantages and use of LC-DCP and LP for comminuted fracture stabilization have been discussed, but not investigated. The use of LC-DCP-rod constructs (LCR) has neither been described, nor investigated. The use of IN stabilization of femoral fractures has been discussed and investigated. Report of biomechanical data about the specific appliances tested in this study is rare. No direct comparisons of the studied appliances supporting an open fracture gap are found.

Review of the biomechanical literature for purposes of discovering methodology and comparing results was unrewarding and frustrating. The number of biomechanical papers relevant to preparation for and validation of this study was limited. Generally, biomechanical studies lack any standardization of construct preparation and biomechanical testing methodology. Despite recommendations by the AO-ASIF and others concerning appropriate testing methods,[11-16,21] there appears to be no consensus among researchers which would tend to unification of their efforts. Biomechanical reports suffer from variability of testing methods, and results are often reported in the wrong units - most commonly the report of compressive stiffness as an isolated force [e.g. newtons (N), appropriately newton/meter (N/m)] or the report of bending stiffness as a linear force, rather than an angular moment [e.g. Newton-meter (Nm), appropriately Newton-meter per degree (Nm/deg)]. This is likely the result of inappropriate data collection or data transformation. Further, methodology descriptions generally lack sufficient detail in the discussion to allow data/result transformation by the reader for comparison between studies. These problems, which occur through the collective efforts of the investigators, manuscript reviewers, and journal editors alike, make interpretation and comparison of the data difficult. Likely, these problems occur because those involved don't have a firm theoretical grasp on the "mechanics" of biomechanics.

CHAPTER 3

RESEARCH METHODOLOGY

Materials and Methods

Experimental Design Brief

The relative strengths of intact cadaveric canine femurs and six internal stabilization constructs were compared under nondestructive physiologic loading conditions with four isolated forces. Twenty-eight treatment groups (Fig. 6) comprised a factorial arrangement with four loading forces (cranial-caudal and medio-lateral bending (CCB, MLB); axial and

TREATMENTS				
Construct/Load	EC	AC	MLB	CCB
FEM	F-EC	F-AC	F-MLB	F-CCB
IN	IN-EC	IN-AC	IN-MLB	IN-CCB
LP	LP-EC	LP-AC	LP-MLB	LP-CCB
LCR	LCR-EC	LCR-AC	LCR-MLB	LCR-CCB
PR	PR-EC	PR-AC	PR-MLB	PR-CCB
LC	LC-EC	LC-AC	LC-MLB	LC-CCB
DCP	DCP-EC	DCP-AC	DCP-MLB	DCP-CCB

Figure 6. Treatment groups. Twenty-eight treatment groups comprised a factorial arrangement with four loading forces [cranial-caudal and medio-lateral bending (CCB, MLB); axial and eccentric compression (AC, EC)] and seven constructs [intact femurs (FEM); dynamic compression plate (DCP); limited contact - dynamic compression plate (LC); DCP with IM pin (PR); LC-DCP with IM pin (LCR); lengthening plate (LP); and interlocking nail (IN)].

eccentric compression (AC, EC)] and seven constructs [intact femurs (FEM); dynamic compression plate (DCP); limited contact - dynamic compression plate (LC); DCP with IM pin (PR); LC-DCP with IM pin (LCR); lengthening plate (LP); and interlocking nail (IN)]. Thirty-two femurs were subjected to loading in CCB, MLB, AC, and EC with a materials-testing machine (Model TM-S. Instron Corporation, Canton, Massachusetts). A 2cm ostectomy was made to simulate non-reconstructable fracture comminution. Constructs of PR, LCR, LP, and IN were randomly applied to FEM using standard techniques. DCP and LC constructs were created by removal of pins from previously tested PR and LCR constructs. Eight constructs of each design were tested. Structural stiffness was determined as the calculated slope of the elastic portion of the load-deformation curve. Interfragmentary motion was measured as fracture gap collapse. Mean values for biomechanical variables were compared between FEM and ostectomized femur-constructs.

Specimen Preparation

Thirty-two (32) unpaired femurs were collected from skeletally mature, young adult dogs, weighing between 20 and 40 kg. Each of the dogs had been previously used under the approval of the Oklahoma State University Institutional Animal Care and Use Committee, then euthanized for reasons not related to this study. None of the dogs had orthopedic disease or had received treatments that might adversely affect bone strength, based on history, physical examination, and gross bone examination. The femurs were collected immediately following euthanasia, soft tissues removed, and bones wrapped in saline-soaked cloth to preclude dehydration during storage. Femurs were sealed in plastic bags and stored at -20°C, awaiting later use. Collection, labeling, and storage methods were consistent with accepted practices.[14 42 56 75] Labeled femurs were assigned to have one of four constructs (DCP, LC, LP, IN) applied using a random number generator (MS Excel).

econstructable mid-diaphyseal comminution. Plate-rod constructs comprised a n DCP plate (Synthes, Ltd., Paoli, Pennsylvania), secured to the fracture model unicortical screws and two 3.5mm bicortical screws. The central two screw l open in the fracture gap. A 3.2 mm Steinman pin (IMEX Veterinary, Inc., s), occupying approximately 40% of the isthmus diameter was placed om proximal to distal metaphysis along the central medullary, neutral s using a low speed bone drill (250 rpm). Limited contact plate-rod constructs) hole, 3.5mm LC-DCP plate (Synthes), secured to the fracture model with cortical screws. The central two screw holes remained open in the fracture Steinman pin, occupying approximately 40% of the isthmus diameter was ucts of each design (FEM, IN, LP, LCR, PR, LC, DCP) were subjected to each (AC, EC, CCB, MLB) using a materials testing machine (Instron) with 10,000 ell. Construct-force testing was conducted randomly (order selected by Excel™ ıer generator) until all iterations of each construct-force combination had been ach construct was tested similarly. The proximal and distal ends of the femur s) were placed onto the material-testing machine. The Instron was balanced d before each construct-force testing iteration. Constructs were first pre-loaded 11 Lb) prior to testing to remove construct play in the testing machine. Load-lata were collected via monotonic non-destructive loading (single ramp simulate physiologic loading conditions [200N @4.5N/sec (AC, EC), 5Nm ng moments (CCB and MLB) of up to 5Nm at a rate of 0.5Nm/sec. Gap-closing ding, as recommended by AO-ASIF and other biomechanical investigators, was ur-point bending allows a constant bending moment between the two internal and the derived stiffness does not depend upon the exact position of the the appliance. Additionally, 4-point bending generates bending forces most ure loading.[11] Construct footings ensured loading in true CCB or MLB. Instron oller bar contact allowed the construct bending translation in only one- anial-caudal or medio-lateral), while fracture gap collapse occurred in the sion (proximal-distal). An inner loading span of 150mm and an outer loading m created offset lever arms of 25mm, which derived a bending moment of

the geometric linear translation of the weighted absolute values of 3-
ectors at 200 N (compression) and 5 Nm (bending moment). Data
n, before use by SAS software, was performed on Excel spreadsheets.
sis of variance (ANOVA) procedures were performed using PC SAS Version 6.11
. Cary, NC) on data from an 4 x 7 factorial arrangement of treatments
ce combinations) within a randomized block design. Eighty (80) experimental
plied to 32 cadaveric femurs (FEM), with pooled n = 240, df = 239. Barring
etween construct types, major effect determination of overall construct
ross forces could be determined. Barring this, the relative strength of individual
ided with individual forces could be compared. Additionally, the use of multiple

al methods performed were consistent with published fracture stabilization [1,65] Efforts were made to describe biomechanical methods in sufficient detail to ent reproduction and result comparison by future investigators.

men collection, storage, and preparation were much more labor intensive than For this reason, and the negative effect of inherent variability of biological data set variance, I would not recommend cadaveric bone studies to other Bone model use is accepted in human bone-construct biomechanical testing.[1] biomechanical studies, bone model use is a new topic of investigation and is ented. Nevertheless, I would recommend model use over cadaveric specimen

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e discussion and bibliography referencing studies which validate human bone biomechanical studies is found at www.sawbones.com.

loading heads to allow freedom of movement in response to compressive loading.

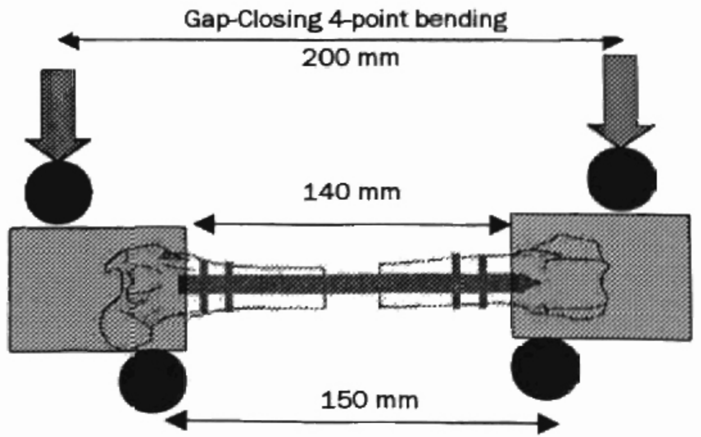

Figure 8. Bending. Gap-closing 4-point bending (MLB, CCB). MLB is depicted.

and represented in Figure 9.

en loaded in compression (Tab.1), all constructs were centrally distracted in a ral direction with medial (trans-cortex) gap collapse, as compressive loading was ransmitted through the construct as a ML bending force. This effect was greater AC due to a longer effective lever arm between the appliance and the effective nt. Under eccentric compression (EC), intact femurs (FEM) and interlocking nails gnificantly stiffer than other constructs. Lengthening plates (LP) were also y stiffer than plate-rod constructs (PR, LCR) and buttress plate constructs (DCP, axial compression (AC), intact femurs (FEM) and lengthening plates (LP) were y stiffer than other constructs. Interlocking nails (IN) and plate-rod constructs (PR, vely weaker bending resistance of the 3.5mm screws. This was noted as ıllapse towards the IN prior to evidence of nail bending. This effect was greatest ng moment was across the screw holes (CCB) and decreased with bending gnment along the screw holes (AC, EC, MLB). This resulted in less stiffness than r IN constructs. Under medial-lateral bending (MLB), intact femurs (FEM) and ; plates (LP) were significantly stiffer than other constructs. Other constructs did strate significant differences in bending stiffness. Under cranial-caudal bending thening plates (LP) were significantly stiffer than all other constructs. Intact M) and LCR constructs significantly stiffer than LP, PR, and buttress plate (DCP, LC). Determination of bending stiffness is summarized: [MLB (FEM > LP >>

s greater than expected due to independent cantilever collapse of proximal ments until the inner cortex engaged the IN; this effect was greatest in CCB. tion for each treatment condition (load-construct combination) is given in Table nted in Figure 10. Under eccentric compression (EC), buttress plate constructs ved significantly more gap motion than plate-rod constructs (PR, LCR), which motion than IN or LP. Under axial compression (AC), no significant differences were observed between constructs. Under medial-lateral bending (MLB), constructs (DCP, LC) allowed significantly more gap motion than other te-rod constructs (PR, LCR) allowed significantly more gap motion than ates (LP), which allowed significantly more gap motion than interlocking nails nial-caudal bending (CCB), DCP and IN constructs allowed significantly more

Summary

chanical testing, data collection and transformation, and statistical analysis ed as discussed in the methodology description. A relatively small variance in is represented by an experimental standard error of 8% of mean. This is equal other representative biomechanical studies. Generally, the use of biologic nds to increased variance in data collection due to individual variability and the f error through numerous sources: collection, storage, freeze-thaw cycles, bone ral density differences, isthmus diameter.[11, 14,42,56,75] Dog age does not have ect on canine bone's structural properties.[11,51,56] These possible sources of icipated and mitigated through meticulous specimen handling, definition of ɔcking nail motion, especially in CCB, was unexpected. The effect of

ragment rotation about the locking screws is discussed above. The effect of IN

struct stability has probably been underestimated in previous studies.[8,9] This

expected to increase, within limits, proportionately with isthmus-nail diameter

the distance the fragments can collapse prior to inner cortex engaging the

, plate-rod combinations performed as would be expected based on inertial

r a bone lengthening plate (without fracture gap screw holes) of similar size.

n that 4.5mm narrow plates should outperform 3.5 mm plate-rod constructs,

outperform buttress 3.5mm plates, is justified using biomechanical principles.

fect (per construct) comparisons can not be made, IN and LP constructs

ormed plate-rod constructs, which outperformed buttress plate constructs.

ruct stiffness. Compressive stiffness (N/m) and bending stiffness (Nm/deg) calculated as the slope of the elastic
ad-deformation curve. Bars represent mean values. Bold lines represent significant differences between means
ing forces = [cranial-caudal and medio-lateral bending (**CCB, MLB**); axial and eccentric compression (**AC, EC**)].
tact femurs (**FEM**); dynamic compression plate (**DCP**); limited contact - dynamic compression plate (**LC**); DCP with
pin (**PR**); LC-DCP with pin (**LCR**); lengthening plate (**LP**); interlocking nail (**IN**)).

agmentary motion. Interfragmentary motion (mm) measured as maximum fracture gap collapse. Bars represent d lines represent significant differences between means ($p < 0.05$). Loading forces = [cranial-caudal and medio- CB, **MLB**); axial and eccentric compression (**AC, EC**)]. Constructs = [intact femurs (**FEM**); dynamic compression ed contact - dynamic compression plate (**LC**); DCP with intramedullary pin (**PR**); LC-DCP with pin (**LCR**); lengthening cking nail (**IN**)].

e plates and clinical application of such plates can be challenging, requiring
tissue disruption and plate contouring. While the size of femurs used in this
sistent with other studies, lengthening plate (4.5mm narrow LP) placement in
iired such contouring and pushed the limits of acceptable plate size for the
As an alternative allowing less technically demanding plate application and
otion of the fracture site, 3.5 mm plate-rod constructs (PR, LCR), which allow
s of inertia equivalent to LPs of smaller, unavailable sizes, were also tested.[40]
n narrow or 3.5mm broad, DCP or LC plates were not used. Controversy exists
e regarding the relative biomechanical merits of 4.5 mm narrow versus 3.5mm
[9,77] Nevertheless, an LP with solid fracture gap coverage offers an intuitively

:ructs to stabilize until clinical healing occurs.[6,10,12,47,60,72,84] An open fracture
is chosen to simulate irreducible comminution as has been performed in other
;.[8,9,24,25,41] Femur size, collection, storage, and preparation was consistent with
;.[8,9,24,41,65] Biomechanical testing of femurs and constructs was also consistent
ıblished studies in the literature, although there seems to be no apparent
the biomechanical evaluation of fixation constructs.

ose to evaluate the relative merits of the selected constructs in terms of
ness and IFM. Structural stiffness is the biomechanical parameter which best

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all currently available options ... :" The VETFIX system is a new fracture
ystem designed for use in the studied fracture model. Synthes was contacted
ıew 3.5mm and 4.5 mm VETFIX systems for evaluation. VETFIX systems were
or this study.

in the other tested forces, and is not routinely evaluated in biomechanical

Compressive loads of 200N (21Kg, 45Lb) and bending moments of 5 Nm were

this is consistent with similar studies and physiologic loading conditions.[8,9,24,25]

agmentary motion was evaluated because its magnitude has been shown to be

oth fracture fixation failure and increased fracture osteosynthesis.

ary motion at a rate of greater than 2% is known to exceed bone's stress limit

on and leads to callus formation or fracture healing

.[20,47,57,60,72,73,84] However, controlled interfragmentary micromotion has been

biologic osteosynthesis as a means to improved bone healing.[5,23,48,68,69,73]

s support these recommendations.[17,22,52,66,86] For these reasons, IFM is a

tion when comparing the relative merits of fixation devices. As noted in this l compression (AC), intact femurs (FEM) and lengthening plates (LP) were

ffer than other constructs. Interlocking nails (IN) and plate-rod constructs (PR,

significantly stiffer than buttress plate constructs (DCP, LC). Constructs

ght be predicted based on their biomechanical properties (Appendix A)[63,76]

tion of greater LP stiffness than IN under AC. A wide diameter IN loaded in AC

m and should be expected to have virtually no deformation under physiologic

ons (< 200N) because of the high material strength of 316L steel. However,

ews are subjected directly to bending forces and collapse as a combined

ir smaller diameter (3.5mm) and the lever arm between the longitudinal axis

. The lever arm and the screws' proportional bending deformation is

ıpse towards the IN prior evidence of nail bending. This effect was greatest
; moment was across the screw holes (CCB) and decreased with bending
ment along the screw holes (AC, EC, MLB). This resulted in less stiffness than
N constructs. Under medial-lateral bending (MLB), intact femurs (FEM) and
lates (LP) were significantly stiffer than other constructs. Other constructs did
ate significant differences in bending stiffness. Under cranial-caudal bending
ening plates (LP) were significantly stiffer than all other constructs. Intact
and LCR constructs were significantly stiffer than LP, PR, and buttress plate
CP, LC). Given the preceding discussion, the behavior of each construct under
as expected or can be explained.

s generally performed on par with DCPs. This is not consistent with Jain's hile steel or titanium LC-DCPs or DCPs performed equally well in the losed- gap canine radial fractures, DCPs provided more stiffness in an open-Similarly, another recent study found that naked 3.5mm steel LC-DCPs were iff as naked 3.5mm steel DCPs in 4-point bending.[55] The expectation is that ending would be a more representative predictor of the plates' performances n buttress across a large, open fracture gap. However, in two other studies, ıd 4.5mm sDCP had similar bending stiffness in a 1mm gap model,[1] and ıd 4.5mm tDCP had nearly identical bending stiffness in a closed gap model.[59] consistent with these studies, which lead to an expectation that DCPs perform cking nails generally performed as expected based on their large area moment measured stiffness less than intact FEM, commensurate with LPs, and better l constructs and buttress-plate constructs. As noted above, the role of tex diameter and loading direction on screw stiffness cannot be discounted as distal fragments may demonstrate independent cantilever bending with a locking screws, decreasing overall construct stiffness. Under greater forces will collapse in bending until the inner cortex engages the IN. This effect was bending moment was across the screw holes (CCB) and decreased with ent alignment along the screw holes (AC, EC, MLB). Interlocking nail IFM, CB, was similarly unexpected, but was proportional to unexpected decreases in for by the three nail configuration used and by the method of IFM

. While hard to verify, the IFM measurements reported by Bernarde appear to

ılation to include cantilever movement of the entire bone-construct, while our

surements are for relative fracture gap motion factoring out gross construct

inically, callus formation noted during buttress construct healing supports the

ıicromotion as demonstrated in our study. Of note is that under these

ading conditions, all mean motion measurements were less than 1 mm except

ates (LC, DCP). This again tenders reservations concerning the use of buttress

repair of highly comminuted femoral fractures.

uct behavior when loaded discounts the effect of bone-appliance interface effect was most evident in IN construct fragment cantilever motion about the IN exceptions aside, our hypotheses were validated.

Clinical implications

no single fixation device clearly outperforms the others, generally intact femur s and LPs, which outperform plate rod constructs, which outperform buttress lly these results imply that: 1) No construct performs at the level of FEM, and confinement is essential to prevent construct failure. This finding also destructive-load testing in eccentric compression is a closer approximation of ions. While the use of a single screw at one end of the IN has been noted to not lter construct stability and is preferred to placing a screw adjacent to the [5,26,27,37] the results of this study and Bernarde's studies raise questions about having been determined using human IN models. The effect of single versus s in Dueland IN-construct stiffness and fatigue life should be assessed.

gestion that medial plating of the femur may be stronger against physiologic ntric compression leading to bending) in the face of the lack of intact medial rt has been theoretically modeled and suggested.[12] Femurs are usually plated use it places the plate in tension (if the medial cortex is intact), the approach is

al of this study was to compare the relative strengths of intact cadaveric
and six internal stabilization constructs under nondestructive physiologic
ions with four isolated forces. We hypothesized that FEM would outperform all
d that the stabilized gap-ostectomized femur constructs would have
l characteristics commensurate with the appliances' material strengths. This
s largely validated.

ically, the results of this study are summarized as follows [Significant
e indicated by ">>" or "<<".]: Stiffness - EC (FEM > IN >> LP >> LCR > PR > LC

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x 140 mm	140	8			
Pin, 3.12 mm (⅛")	140-160	3.12			

roperties:

ial	Density gm/ml	Strength (tensile) MPa	E (tensile) MPa	Strength (flex) MPa	E (flex) MPa	Strength comp) MPa	E (comp) MPa
	38.9	5.8 E02	1.9 E05			?	
(Human)	2.0	1.3 E02	1.7 E04			1.9 E02	
st	1.7	2.9 E01		4.8 E01	2.5 E03	7.6 E01	
		4.8 E01		7.2 E01	2.1 E03	7.9 E01	

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